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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,653	09/07/2007	Martha Karen Newell Rogers	LA-7450-112WO	6541
7590 Robert Berliner Fulbright & Jaworski 555 South Flower Street Forty-First Floor Los Angeles, CA 90071			EXAMINER HAMA, JOANNE	
			ART UNIT 1632	PAPER NUMBER
			MAIL DATE 02/18/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/556,653	Applicant(s) NEWELL ROGERS ET AL.	
	Examiner JOANNE HAMA	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-25,31-33,36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,3-25,31-33,36 and 37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

This Application, filed September 7, 2007 is a 371 of PCT/US04/14996, filed May 12, 2004 and claims priority to US Provisional Application 50/470,046, filed May 13, 2003.

Applicant filed amendments to the claims on November 12, 2005. Claims 2, 26-30, 34, 35, 38 are cancelled. Claims 1, 3-8, 10, 12, 25 are amended.

In the claim amendments filed November 12, 2005, it is noted claims 9, 11, 13-24, 31-33, 36, 37 are missing status identifiers. Upon amendment of claims, Applicant must use the appropriate status identifiers for the claims or risk non-entry of the amendments. See 37 CFR 1.121. It is noted that claims 9, 11, 13-24, 31-33, 36, 37 appear to be original claims and must be indicated as "original".

Claims 1, 3-25, 31-33, 36, 37 are pending.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1, 3-12, drawn to a method of diagnosing a pre-disposition to a chromosomal abnormality associated with Down Syndrome in a fetus.

Group 2, claim(s) 13-15, drawn to a method of modifying an oocyte or an embryonic cell comprising microinjecting heterologous mitochondria into an oocyte or embryonic cell.

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Group 3, claim(s) 16, 17, drawn to a modified stem cell comprising heterologous mitochondria.

Group 4, claim(s) 18-21, 36, drawn to a method for promoting tissue generation, wherein the tissue is neural.

Group 5, claim(s) 22-24, drawn to a screening assay comprising identifying a mitochondrial deletion.

Group 6, claim(s) 25, drawn to a kit for assessing mitochondrial status in a maternal sample.

Group 7, claim(s) 31-33, drawn to a neural stem cell comprising an isolated UCP4 gene.

Group 8, claim(s) 37, drawn to a modified oocyte or embryonic cell comprising heterologous mitochondria.

The inventions listed as Groups 1-8 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature is a disruption in mitochondrial DNA being indicative of Down Syndrome. At the time of filing, Arbuzova et al., 2001, Clin. Genet., 60: 456-462 teach that mutations in mitochondrial DNA have a role in the etiology of Down Syndrome (Arbuzova et al., abstract).

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Claim 1 of Invention 1 is drawn to two distinct ways that Down Syndrome can be diagnosed by (a) a mitochondrial deletion, or b) a lower than normal baseline of mitochondrial membrane potential) and one must be elected.

Claims 5, 6 of Invention 1 are drawn to two different times when the diagnostic method is carried out and one must be elected.

Claims 8, 10 of Invention 1 are drawn to two ways that mitochondrial membrane potential status is determined and one must be elected.

Claim 11 of Invention 1 is drawn to a number of cell surface molecules and one must be elected.

Claim 25 of Invention 6 is drawn to two distinct ways that Down Syndrome can be diagnosed (a) a mitochondrial deletion, or b) a lower than normal baseline of mitochondrial membrane potential) and one must be elected.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

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are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic:

Claims 1, 3-7 of Invention 1 are generic for different ways that Down Syndrome can be diagnosed.

Claims 1, 3, 4, 7-12 of Invention 1 are generic for times when the diagnostic method is carried out.

Claims 1, 3-7, 12 of Invention 1 are generic for ways of determining mitochondrial membrane potential status.

Claims 1, 3-12 of Invention 1 are generic for cell surface molecules.

Claim 25 of Invention 6 is generic for two ways that Down Syndrome can be diagnosed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

MPEP 1893.03(d) states: If an examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), the nonelected invention(s) should be considered for rejoinder. Any nonelected product claim that requires all the limitations of an allowable product claim,

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and any nonelected process claim that requires all the limitations of an allowable process claim, should be rejoined. See MPEP § 821.04 and § 821.04(a). Any nonelected processes of making and/or using an allowable product should be considered for rejoinder following the practice set forth in MPEP § 821.04(b).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Mondays, Tuesdays, Thursdays, and Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has

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been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Joanne Hama/
Primary Examiner
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